Aventis Farma Sa (M) Sdn Bhd & Anor v Rohibul Sabri bin Abas @ Megat (t/a as Dabur Enterprise) & Anor

HIGH COURT (KUALA LUMPUR) — SUIT NO D1–22–317 OF 2006
VINCENT NG J
27 SEPTEMBER 2007

Civil Procedure — Injunction — Balance of convenience — Infringement of patent — Whether damages adequate compensation — Whether infringement of patent would cause irreparable damage to the plaintiffs' goodwill and reputation — Whether proprietary rights in patent can be compensated by damages

Patents — Infringement — Presumption — Whether statutory presumption applicable in an interlocutory application — Whether onus to discharge statutory presumption a legal burden — Patents Act 1983 s 36(4)

Patents — Infringement — Process patent — Whether process patent protected process as well as product directly obtained from patented process — Whether injunction can be granted in respect of product obtained from patented process

The second plaintiff was a multinational pharmaceutical company involved in active research, development, manufacture and distribution of pharmaceutical products. The first plaintiff was a Malaysian registered subsidiary of the second plaintiff. The first plaintiff was the registrant of the marketing approval of the drug Taxotere®, and had been marketing Taxotere® since 1997. The active ingredient in Taxotere® was docetaxel trihydrate ('DT'). The Malaysian Patent No MY-118481–A ('MY'481A') being a process for the manufacture of DT was granted to the second plaintiff on 30 November 2004. The second plaintiff had also became the registrant of US Patent No 6022985 on 8 February 2000 for the manufacture of DT. In late 2005, the second defendant and the first defendant, as the second defendant's agent, started selling the drug Daxotel in Malaysia. The plaintiffs claimed that the defendants had infringed the plaintiffs' MY'481A patent. The active ingredient in Daxotel was also DT. The plaintiffs also claimed that Daxotel is manufactured using processes similar to that used in the manufacture of Taxotere. Accordingly, the plaintiffs filed an application for injunction and sought, inter alia, to restrain the defendants by themselves or their officers or servants or agents from offering for sale or selling Daxotel or authorising others so to offer for sale, pending the disposal of the present suit.

The defendants contended that the process employed by the second defendant to manufacture the active ingredient DT in Daxotel was different and distinct from the process that was patented to the second plaintiff under MY'481A, and as such there was no infringement of the said patent.

Held, allowing the plaintiffs' application:

(1) Section 36(4) of the Patents Act 1983, imposes on the defendants an onus to discharge a statutory presumption that they had infringed the plaintiffs' patent No MY'481A. The term 'any proceedings' in this provision should obviously include proceedings such as interim injunctions as in the instant case. The burden imposed on a defendant was a legal burden, save that due to the absence of oral evidence at the interlocutory stage of the proceedings the defendant need only discharge such presumption upon a prima facie basis. If the court was to accept the defendant's submission that a registered patentee could invoke the aforesaid section only at the trial stage of the proceedings then such patent registration would be rendered virtually nugatory (see para 16).

(2) A process patent would have the combined effect of protecting the process as well as the product which was directly obtained from the patented process. In this regard, the plaintiffs were seeking to prevent the sale of Daxotel, which was a product directly obtained from the patented process for DT. Thus, the plaintiffs were not seeking a back door remedy as alleged by the defendants, since the scope of a process patent also covers the product obtained directly from the process. The patent once granted was prima facie valid. Thus the defendants' claim that the grant of the US patent was prima facie evidence of non-infringement was not only incorrect in law but untenable as this case was concerned with a Malaysian patent vis-a-vis Malaysian courts (see para 17).

(3) Based on the report of the independent expert, the defendants' process would, bereft of any oral testimony, appear to infringe the plaintiffs' MY'481A patent. Also, the fact that the second defendant held a US patent was quite irrelevant to the question of infringement of the Malaysian patent, since the *lex loci* of the cause of action (law of the country in which the breach occurred) was Malaysia while the *lex fori* of this action (law of the country where the action was brought) was also Malaysia, and, a fortiori, it was indeed a Malaysian registered patent (being MY'481A) that was sought to be enforced (see para 20).

(4) The defendants' activities in manufacturing and selling Daxotel will destroy the plaintiffs' proprietary rights in the patent especially as they

have claimed that their product was cheaper than the plaintiffs'. The plaintiffs will amongst other things lose market share in Malaysia. If the defendants were allowed to continue to sell Daxotel, having incurred virtually no up-front investment relating to research and development, the plaintiffs will be forced to match the generic-pricing in order to compete. This lower price, would be difficult, if not possible to restore to the current pre-generic price level, should the plaintiffs succeed at the trial in obtaining a permanent injunction (see para 24).

(5) The first defendant only began selling Daxotel in Malaysia in October 2005 whereas the plaintiffs' product Taxotere® had been in Malaysian market since 1997. Since the defendants had not expended significant resources in the development and marketing of their product their probable losses, even though quantifiable, could not be as grave as the plaintiffs' (see para 27).

(6) Since the injunction sought was only in respect of Daxotel, the defendants could continue selling their many other drugs to purchasers, thereby maintaining the existing relationships. This will not harm the defendants' trade in a manner which could not be compensated in damages. In the circumstances, they would not be adversely affected substantially by the injunction. Thus, the balance of convenience favoured the plaintiffs (see para 28).

(7) The defendants' contention that public interest would be better served if they were allowed to continue selling Daxotel, since it costs substantially less to cancer patients than the plaintiffs' Taxotere was devoid of merit. Obviously, the strong public interest factor in protecting the integrity of the patent systems and foreign commitments through mutual protocols, etc, would generally prevail over other public interest considerations. This was also underscored by the consideration that it was inimical to Malaysian economic interest not to protect its own patent system. To deny an interim injunction in the instant case would adversely impact upon the public interest in preserving intellectual property rights (see paras 29–30).

[Bahasa Malaysia summary

Plaintif kedua adalah sebuah syarikat farmaseutikal multinasional yang terlibat secara aktif dalam penyelidikan, pembangunan, pembuatan dan pengedaran produk-produk farmaseutikal. Plaintif pertama merupakan subsidiari plaintif kedua yang didaftarkan di Malaysia. Plaintif pertama adalah pemilik berdaftar kelulusan pemasaran bagi ubat Taxotere®, dan telah memasarkan Taxotere® semenjak 1997. Bahan aktif di dalam Taxotere® adalah docetaxel trihydrate ('DT'). Paten Malaysia No MY–118481–A ('MY'481A') yang merupakan proses bagi pembuatan DT telah diberikan

kepada plaintif kedua pada 30 November 2004. Plaintif kedua juga menjadi pemilik berdaftar Paten US No 6022985 pada 8 Februari 2000 bagi pembuatan DT. Pada akhir tahun 2005, defendan kedua dan defendan pertama, sebagai ejen defendan kedua mula menjual ubat Daxotel di Malaysia. Plaintif menuntut bahawa defendan-defendan telah melanggar paten MY'481A plaintif-plaintif. Bahan aktif dalam Daxotel juga adalah DT. Plaintif-plaintif juga menuntut bahawa Daxotel dibuat menggunakan proses yang sama dengan Taxotere®. Selanjutnya, plaintif-plaintif telah memfailkan satu permohonan injunksi dan memohon, antara lain, untuk menahan defendan-defendan sendiri atau pegawai-pegawai mereka atau kakitangan-kakitangan atau ajen-ajen daripada menawarkan untuk jualan atau jualan Daxotel atau memberikan kuasa kepada orang lain untuk penawaran penjualan, sementara penyelesaian kes ini. Defendan-defendan menegaskan bahawa proses yang digunakan oleh defendan kedua untuk membuat bahan aktif DT dalam Daxotel adalah berlainan dan berbeza daripada proses yang telah dipatenkan kepada plaintif kedua di bawah MY'481A, dan oleh itu tiada perlanggaran terhadap paten tersebut.

Diputuskan, membenarkan permohonan plaintif-plaintif:

(1) Seksyen 36(4) Akta Paten 1983, telah mengenakan ke atas defendan-defendan tanggungjawab untuk melepaskan anggapan statutori bahawa mereka telah melanggar paten MY'481A plaintif-plaintif. Terma 'any proceedings' dalam peruntukan ini seharusnya jelas termasuk prosiding seperti injunksi interim seperti kes sekarang ini. Beban yang dikenakan terhadap defendan adalah beban perundangan kecuali jika tiada keterangan lisan pada peringkat prosiding interlokutori defendan hanya perlu melepaskan anggapan tersebut atas dasar prima facie. Jika mahkamah menerima hujahan defendan bahawa pemunya paten boleh membangkitkan seksyen tersebut hanya pada peringkat bicara prosiding oleh itu paten sedemikian akan menjadi sia-sia sebenarnya (lihat perenggan 16).

(2) Paten proses mempunyai kesan gabungan melindungi proses dan juga produk yang didapati secara terus daripada proses yang dipatenkan. Dalam perkara ini, plaintif memohon untuk menghalang penjualan Daxotel, iaitu produk yang diperolehi daripada proses yang dipatenbagi DT. Oleh itu, plaintif-plaintif bukan cuba mendapatkan remedi 'back door' seperti yang didakwa oleh defendan-defendan, memandangkan skop paten proses juga meliputi barang yang didapati secara terus daripada proses. Paten apabila sahaja diberikan adalah prima facie sah. Oleh itu dakwaan defendan-defendan bahawa pemberian paten AS adalah keterangan prima facie bukan pelanggaran adalah bukan sahaja tidak betul dari segi undang-undang malah tidak dapat dipertahankan

kerana kes ini adalah berkaitan dengan paten Malaysia vis-à-vis mahkamah Malaysia (lihat perenggan 17).

(3) Berdasarkan laporan pakar bebas, proses defendan akan tanpa apa-apa testmoni lisan, melanggar paten MY'481A plaintif-plaintif. Juga, fakta bahawa defendan kedua memegang Paten US adalah agak tidak relevan kepada soalan perlanggaran paten Malaysia, kerana *lex loci* kausa tindakan (undang-undang bagi negara di mana perlanggaran berlaku) adalah Malaysia sementara itu *lex fori* tindakan ini (undang-undang bagi negara di mana tindakan dimulakan) juga adalah Malaysia dan dengan sebab yang kuat ia sudah tentu paten Malaysia yang berdaftar (iaitu MY'481A) yang dipohon untuk dikuatkuasakan (lihat perenggan 20).

(4) Aktiviti-aktiviti defendan-defendan dalam pengilangan dan penjualan Daxotel akan memusnahkan hak pemilikan plaintif dalam paten terutamanya kerana mereka mendakwa bahawa produk mereka adalah lebih murah daripada produk plaintif-plaintif. Plaintif-plaintif antara lain akan kehilangan sebahagian pasaran di Malaysia. Jika defendan dibenarkan untuk terus menjual Daxotel, dengan tiada tanggungan pelaburan pendahuluan berkenaan dengan penyelidikan dan pembangunan, plaintif-plaintif akan dipaksa untuk berlawan dengan harga generik untuk bersaing. Harga yang rendah ini akan menyusahkan, jika tiada kemungkinan untuk mengembalikan kepada paras harga pra-generik sekarang sekiranya plaintif-plaintif berjaya dalam perbicaraan mendapatkan injunksi kekal (lihat perenggan 24).

(5) Defendan pertama hanya mula menjual Daxotel di Malaysia pada Oktober 2005 manakala produk plaintif Taxotere® telah berada di pasaran Malaysia semenjak 1997. Memandangkan defendan tidak meluaskan sumber-sumber dalam pembangunan dan pemasaran produk mereka, kerugian yang mungkin dialami, walaupun boleh dinyatakan kuantitinya, tidaklah seteruk plaintif-plaintif (lihat perenggan 27).

(6) Memandangkan injunksi yang dipohon hanyalah berkenaan dengan Daxotel, defendan boleh terus menjual ubatan mereka yang lain kepada pembeli-pembeli dan dengan itu mengekalkan hubungan yang sedia ada. Ini tidak akan memudaratkan perniagaan defendan dalam keadaan yang tidak boleh dipampas dengan ganti rugi. Di dalam keadaan ini, ia tidak akan terjejas dengan teruk oleh injunksi. Oleh itu, imbangan kemudahan berpihak kepada plaintif (lihat perenggan 28).

(7) Hujahan defendan-defendan bahawa adalah lebih baik demi kepentingan awam jika mereka dibenarkan untuk meneruskan menjual Daxotel, memandangkan kosnya lebih murah kepada pesakit-pesakit kanser daripada Taxotere plaintif-plaintif adalah tidak bermerit.

Adalah jelas, faktor kepentingan awam yang kuat dalam melindungi intergriti sistem paten dan komitmen asing melalui protokol bersama dan sebagainya, biasanya boleh mengatasi pertimbangan kepentingan awam yang lain. Ini juga digariskan oleh pertimbangan bahawa ia adalah memudaratkan kepentingan ekonomi Malaysia sekiranya tidak melindungi sistem patennya sendiri. Untuk menolak injunksi interim dalam kes ini akan memberikan impak yang buruk kepada kepentingan awam dalam mengekalkan kepentingan harta intelek (lihat perenggan 29–30).]

Notes

For cases on balance of convenience, see 2(2) *Mallal's Digest* (4th Ed, 2007 Reissue) paras 2907–2915.

For cases on infringement generally, see 10 *Mallal's Digest* (4th Ed, 2007 Reissue) paras 1092–1109.

For cases on interim injunction, see 2(2) *Mallal's Digest* (4th Ed, 2007 Reissue) paras 3115–3187.

For cases on process patent, see 10 *Mallal's Digest* (4th Ed, 2005 Reissue) paras 1099–1100.

Cases referred to

American Cyanamid Co v Ethicon Ltd [1975] 1 All ER 504; [1975] AC 396 (refd)

Americaya Singapore Pte Ltd v Americaya Malaysia Sdn Bhd [1994] 1 MLJ 695 (refd)

Belfast Ropework Co Ltd v Pixdane Ltd [1976] FSR 337 (refd)

Carroll & Ors v Tomado Ltd [1971] RPC 401 (refd)

Cayne & Anor v Global Nature Resources Plc [1984] 1 All ER 225 (refd)

EAR Corporation v Protector Safety Products (UK) [1980] FSR 574 (refd)

Eurogenetics NV/Ratiopharma v Lundbeck 8 October 2003 case no 03/454/C (unreported) (refd)

Improver Corp & Ors v Raymond Industrial Ltd & Anor [1989] 1 HKC 397 (refd)

NWL Ltd v Woods, NWL Ltd v Nelson & Anor [1979] 3 All ER 614; [1979] 1 WLR 1294 (refd)

Peaudouce SA v Kimberly-Clark Ltd [1996] FSR 680 (refd)

SAP (M) Sdn Bhd v I World HRM Net Sdn Bhd & Anor [2006] 2 MLJ 678 (refd)

Smithkline Beecham Plc v Generic (UK) Ltd [2001] Chancery Division (Patent Court) (refd)

Legislation referred to

Patents Act 1983 ss 36(3)(a), 36(3)(b), 36(4), 58

Khoo Guan Huat (Marie Julie Wan Ullok with him) (Skrine) for the plaintiffs. Samuel Gerad (Miranda & Samuel) for the defendants.

Vincent Ng J:

[1] Before I proceed to the substantive issues, I think it is appropriate here to make certain observations pertaining to the nature of the prayers for injunction that the plaintiffs had sought to move this court in their inter partes application in encl 7. The orders prayed for against the defendants read as follows:

(i) an injunction pending trial to restrain the defendants whether by themselves, their directors, officers, servants or agent or any of them in combination or otherwise from:

(a) directly or indirectly using the process in Malaysian Patent No MY–118481–A,

(b) making, procuring the manufacturing of, importing, exporting, distributing, marketing, offering for sale, selling, using and or howsoever dealing with any form whatsoever

(1) DAXOTEL, or

(2) Any product containing the ingredient docetaxel trihydrate manufactured from the patent process.

(c) authorising others to make, procure the manufacture of, import, export, market, offer for sale, sell, use and/or howsoever deal with in any form whatsoever:

(1) DAXOTEL, or

(2) Any product containing the ingredient docetaxel trihydrate manufactured from the patented process.

(ii) an order for delivery up to the court and subject to further directions from the court, all packaging, vials, concentrate, solvent, marketing materials, patient information leaflets, literature, brochures, advertisements, compact or optical discs and/or promotional materials containing or referring to DAXOTEL, and/or any product containing docetaxel trihydrate manufacture using the patented process and to affirm, file into court and serve on the plaintiffs' solicitors an affidavit to state compliance with the same within 14 days of the order;

(iii) an order for delivery up to the court and subject to further directions from the court, all relevant documents related to the dealings in DAXOTEL, and/or any product containing docetaxel trihydrate manufactured using the patented process, including but not limited to custom clearance documents, invoices, purchase orders, receipts, shipping documents, bills of lading, financial record and correspondences that are either jointly or severally in the possession, custody or control of the defendants, their officer, employees, servants, or agents and to affirm, file into court and serve on the plaintiffs' solicitors an affidavit to state compliance with the same within 14 days of the order.

(iv) costs and incidental to this application; and

(v) that both parties have liberty to apply.

[2] However, having perused the prayers sought for in its original form, I found this to be a typical application for injunction where, even before a judge could embark upon his duty to determine whether or not to grant the injunction as guided by the principles enunciated in *American Cynamid*, he must first look at the scope and extent of each principal order sought for, so as to envisage whether any problem may arise on the implementation or supervision of the order if granted. At the commencement of the hearing on 25 May 2006, when I pointed out to counsel for the plaintiffs that though it is common ground of both parties that Daxotel is manufactured in India, yet his clients had also sought to restrain 'the defendants from making, procuring the manufacturing of Daxotel or ...', which would, if granted, entail execution and enforcement of the order against manufacturing activities conducted outside the purview of the Malaysian court's jurisdiction, counsel for plaintiffs promptly applied for an adjournment to make the necessary amendments to encl 7. Hence, on 9 August 2006, vide encl 23 and by consent, prayer (i) of encl 7 was amended by my learned Deputy Registrar to read as follows:

(1) An injunction to restrain the first and second defendants, whether by themselves, their directors, officers, servants or agents or any other of them in combination or otherwise howsoever from:

(i) offering for sale, *or selling.*

1. DAXOTEL ...

(ii) authorizing others to offer for sale,

1. DAXOTEL ...

(2) That costs of and incidental to this application shall be paid by the defendants to the plaintiffs.

(3) That both parties have liberty to apply.

(4) Such further or other relief as the honourable court deems fit and proper to grant.

The grounds of the application are as follows:

1. the Malaysia Patent No MY–118481–A ('MY'481 Patent') has been granted to the second plaintiff;
2. the MY'481 Patent claims a process for the manufacture of docetaxel trihydrate;
3. the second plaintiff is the manufacture of and the first plaintiff is the registrant of the marketing approval of the drug Taxotere®;
4. the active ingredient in Taxotere® is docetaxel trihydrate;
5. the second defendant, and the first defendant, as agent of the second defendant are, among others offering for sale, and selling the drug Daxotel;
6. the active ingredient in Daxotel is docetaxel trihydrate;
7. the defendants have infringed the MY'481 Patent;
8. the continued infringement activities of the defendants have caused the plaintiffs to suffer substantial and irreparable losses.

The further grounds in support of this application are contained in the affidavit of CHUA YOONG SAENG filed herein.

Dated 16 March 2006

This *amended* summons is taken out by Messrs Skrine, Unit No 50–8–1, 8th Floor, Wisma UOA Damansara, 50, Jalan Dungun, Damansara Heights, 50490 Kuala Lumpur, solicitors for the plaintiffs abovenamed. (KGH/SS/2053776.1) a-docasic-5(in)

The affidavit of CHUA YOONG SAENG affirmed on the 16 March, 2006 and filed herein will be read in support of this application.

THE PLAINTIFFS' CASE

[3] The second plaintiff, a multinational pharmaceutical company with headquarters in France, is involved in active research, development, manufacture and distribution of pharmaceutical products. The first plaintiff, a company registered under the Malaysian law, is a subsidiary of the second plaintiff. The second plaintiff claims to be the third largest pharmaceutical

group in the world and the largest in France and Europe which has commercial presence in approximately 85 countries including Malaysia. The second plaintiff is a manufacturer of key pharmaceutical products which include amongst others, Taxotere® for oncology, Allergra® for allergies and Lantus® for diabetes. The first plaintiff is the registrant of the marketing approval of the drug Taxotere®, and has been marketing Taxotere® since 1997. The active ingredient in Taxotere® is docetaxel trihydrate ('DT'). The Malaysian Patent No MY'481A being a process for the manufacture of DT was granted to the second plaintiff on 30 November 2004. The second plaintiff also became the registrant of US Patent No 6022985 on 8 February 2000 for the manufacture of DT.

[4] Recently, the plaintiffs discovered that the second defendant and the first defendant as the second defendant's agent, have been offering for sale and was selling the drug dexoted since late 2005. The active ingredient in Daxotel is also DT. The plaintiffs claimed that both the first and the second defendants have infringed the plaintiffs MY'481A Patent registered in Malaysia. Accordingly, the plaintiffs sought, inter alia, to restrain the defendants by themselves or their officers, or servants or agents from offering for sale, or selling Daxotel, or authorising others so to offer for sale.

COMMON GROUND

[5] At the outset of the hearing of the application before me, both parties through their counsel agreed to the following as common ground between the parties, that:

(1) the first plaintiff is the registrant of the marketing approval of the drug Taxotere®;

(2) on 30 November 2004 the second plaintiff became the registrant of Malaysian Process Patent No MY'481A for the manufacture of docetaxel trihydrate ('DT');

(3) the active ingredient in both Taxotere® and Daxotel is DT;

(4) Taxotere® is manufactured in France and Daxotel in India; and

(5) the second defendant started selling Daxotel in Malaysia in October 2005 and the first plaintiff has been selling Taxotere® in Malaysia since 1997.

THE DEFENDANTS' CASE

[6] It is the case of the defendants that the defendants' product Daxotel is also a drug to treat cancer. Daxotel is purportedly prepared by a process which was patented in the United States of America (the US Patent). The US

Patent process comprises: step (1) the purification of crude docetaxel, and step (2) the preparation of docetaxel trihydrate by dissolving docetaxel in acetonitrile.

[7] The defendants contend that the plaintiffs' process involves crystallisation from the mixture of C1–3 alcohol, whereas the defendants' method involves precipitation from a mixture of acetonitrile and water. The defendants' further assert that the plaintiffs dry the product in step (1) under a defined condition of, among others, humidity, whereas the defendants' process does not use any conditions for controlling or regulating humidity. Thus, the defendants method in producing docetaxel trihydrate is totally dissimilar from the plaintiffs' patented intellectual property right. In other words the process employed by the second defendant to manufacture the active ingredient DT in Daxotel is different and distinct from the process that was patented to the second plaintiff under patent no MY'481A, and as such there was no infringement of the said patent. It is claimed that the process used by the second defendant is an independent process which has been patented to the defendants in the US on 4 January 2005 vide US of Patent No 6, 838, 569 B2. Their further argument is that the plaintiffs' case is based on process patent and not product patent, which led to the submission that a 'back door' relief has been sought.

THE LAW ON INTERIM INJUNCTION

[8] The principles whether or not to grant an interim injunction has been established in a patent infringement case of *American Cyanamid Co v Ethicon Ltd* [1975] 1 All ER 504; [1975] AC 396 (*'American Cyanamid'*) as follows:

(i) whether any serious question to be tried;

(ii) whether damages could constitute an adequate remedy if the injunction is not granted;

(iii) whether balance of convenience lies in favour of granting the injunction;

(iv) if balance appears even, to consider preservation of status quo;

(v) and if this seems even, to consider, only on a prima facie basis, the relative strengths of each party's case;

(vi) most importantly, at this early stage of the proceedings, the court must be mindful that the relative strengths of each party's case should be considered only on a prima facie basis without dealing with the existing evidence in detail and giving reasoned assessments of the court's views — that is, to try to resolve conflict of evidence on affidavits as to facts.

[9] The current position in both the UK and Malaysia on the law pertaining to interim injunction is the same, ie, the principles enunciated in *American Cyanamid* case are still good law in Malaysia and have been consistently affirmed.

[10] Since dicta of high authority have tended to introduce an unfortunate element of perplexity on the three essential ingredients that the court must consider in its determination whether or not to grant an injunction, it may perhaps be appropriate that I take this occasion to endeavour, through distillation of certain English authorities, to unravel the intricacies of the ingredients, namely, 'a serious issue or question to be tried', 'balance of convenience' and 'adequacy of damages as a remedy'. In respect of the first ingredient, I could do no better than to observe that it was held, in *Cayne & Anor v Global Nature Resources Plc* [1984] 1 All ER 225, that for the purposes of an application for an interlocutory injunction there is a triable issue between the parties if there is a serious question to be tried (ie, one for which there is some supporting material) of which the outcome is uncertain. Accordingly, where the plaintiffs' case relies solely on inference and the defendant has sworn a positive affidavit which, if true and accepted, destroys that inference, the court should not necessarily conclude that the plaintiff has failed to establish a triable issue, because on such an application it is not necessary for the parties to establish firmly the outcome of the case, and the mere fact that a party's case is deposed to does not make it incontrovertible. If the court is in doubt and if the issue seems to be one that is not frivolous, in other words, is one for which there is supporting material, then the court would conclude that there is a triable issue. Where the grant or refusal of an interlocutory injunction will have the practical effect of putting an end to the action, the court should approach the case on the broad principle of what it can do in its best endeavour to avoid injustice, and to balance, the risk of doing an injustice to either party. Further, on 'serious issue or question to be tried' the dicta of Lord Diplock in *American Cyanamid* (at p 510) is also illuminating, when His Lordship said:

> The court, however, expressly deprecated any attempt to fetter the discretion of the court by laying down any rules which would have the effect of limiting the flexibility of the remedy as a means of achieving the objects that I have indicated above. Nevertheless this authority was treated by Graham J and the Court of Appeal in the instant appeal as leaving intact *the supposed rule that the court is not entitled to take any account of the balance of convenience unless it has first been satisfied that if the case went to trial on no other evidence than is before the court at the hearing of the application the plaintiff would be entitled to judgment for a permanent injunction in the same terms as the interlocutory injunction sought. Your Lordships should in my view take this opportunity of declaring that there is no such rule*. The use of such expressions as 'a probability', 'a prima facie case', or a strong prima facie case' in the context of the exercise of a discretionary power to grant an interlocutory injunction leads to confusion as to the object sought to be achieved

A by this form of temporary relief. The court no doubt must be satisfied that the claim is not frivolous or vexatious, in other words, *that there is a serious question to be tried.*

B **[11]** A high degree of analytical prowess, fairness and perceptiveness on the part of the judge is required when considering the three ingredients. I deduce that because, at this stage of the proceedings, the plaintiffs need not show a strong likelihood or probability that his claim would succeed at the trial of the action (only that his claim is not frivolous or vexatious and hence there is a serious question to be tried), it is all the more incumbent on the judge C to carefully and with much perspicacity consider the other two ingredients. Of course, if it has not been demonstrated that there is a serious triable issue the application fails in limine. It must be noted that the *American Cyanamid* guidelines, I think, are based on the proposition that there will be a proper trial at a later stage when the rights of the parties will be determined. The less D elegant way of couching the phrase 'balance of convenience' is 'balance of the risk of doing an injustice'. Whether in the balancing process, it becomes quite clear to the court that there is a substantially greater risk of injustice to the defendant or the plaintiff if the injunction is granted or refused. Thus the ingredient 'balance of convenience' entails the weighing of the plaintiff's need E for protection against the corresponding need of the defendant to be protected against injury resulting from his having been prevented from exercising his own legal rights for which he could not be adequately compensated under the plaintiff's undertaking in damages if the uncertainty were resolved in the defendant's favour at the trial. Since an interlocutory F injunction is merely a holding operation pending a contemplated trial, the degree of likelihood that the plaintiff would have succeeded in establishing his right to injunction if the action had gone for trial is a factor to be brought into the balance of convenience test only if the grant or refusal of the interlocutory injunction will have the practical effect of putting an end to the G action.

[12] In my view, no determination on any injunction application could be properly and justly arrived at without careful consideration also of the two H other vital ingredients, which includes the third ingredient being adequacy of damages as a remedy. On the 'adequacy of damages as a remedy' attention should be directed to the possible result of a postulated trial, first one way and then the other. In this regard, the dicta of Lord Diplock in *American Cyanamid* (at p 510g) apposite. This is what His Lordship had to say:

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> As to that, the governing principle is that the court should first consider whether if the plaintiff were to succeed at the trial in establishing his right to a permanent injunction he would be adequately compensated by an award of damages for the loss he would have sustained as a result of the defendant's continuing to do what was sought to be enjoined between the time of the application and the time of the

trial. *If damages in the measure recoverable at common law would be adequate remedy and the defendant would be in a financial position to pay them no interlocutory injunction should normally be granted, however strong the plaintiff's claim appeared to be at the stage*. If, on the other hand, damages would not provide an adequate remedy for the plaintiff in the event of his succeeding at the trial, the court should then consider whether, on the contrary hypothesis that the defendant were to succeed at the trial in establishing his right to do that which was sought to be enjoined, he would be adequately compensated under the plaintiff's undertaking as to damages for the loss he would have sustained by being prevented from doing so between the time of the application and the time of the trial.

[13] It is only thereafter, if damages after a trial are thought to be inadequate, that one is then enjoined to look at the question of 'balance of convenience'. See the speech of Lord Diplock in *NWL Ltd v Woods, NWL Ltd v Nelson & Anor* [1979] 3 All ER 614; [1979] 1 WLR 1294 wherein His Lordship further explained and applied his judgment in *American Cyanamid*. Indeed, *Kerly's Law of Trade Marks and Trade Names*, by David Kitchin and six others (14th Ed) published by Sweet & Maxwell on 6 September 2006) had suggested, as in the following passage:

In trade mark infringement cases irreparable damage, in this sense, is relatively easily shown, since infringement may easily destroy the value of a mark or at least nullify expensive advertising in a way that is hard to quantify for the purposes of an inquiry into damages. Where all that can be shown, however, is that some damage is likely and ought not to be allowed to go on for too long, an order for a speedy trial may be more appropriate than an injunction. The defendant may meet the application by showing that he genuinely intends to defend and that he also would, if an injunction were granted and were shown at the trial to have been unjustified, suffer damages not reparable by an order for damages under the cross-undertaking that accompanies any interlocutory injunction. If the defendant is able so to do, the matter then depends on the 'balance of convenience', that is, on the relative extent of the damage to one or other party if the injunction is or is not granted. The ability of the parties to meet an order for damages on the scale contemplated will here be relevant. In general, the likelihood that one or other party will succeed at the trial is not a relevant consideration but the likely extent of confusion or deception clearly may be, whilst in cases where the interlocutory proceedings are likely to determine the dispute finally, one way or the other, the probabilities of success are clearly relevant.

Whether there are serious issues to be tried in the instant case

[14] A serious issue or issues to be tried do not ipso facto arise just because a party alleges a certain factual situation to be white whereas the other asserts same to be black. Bereft of viva voce evidence at this stage of proceedings, the duty of the court is to evaluate on a prima facie basis (tentatively) — through a study of all affidavits and the documents, if any exhibited by both sides —

A the cogency of each party's case in order to determine whether serious issues pertinent to the dispute have been raised for trial.

[15] The relevant provision that governs patents in Malaysia is s 36(4) of our Patents Act 1983 ('Act') which is a restatement of art 34 of the Trade Related Aspects of Intellectual Property Rights Agreement ('TRIPS'). Section 36(4) reads:

> For the purposes of this section, if the *patent has been granted in respect of a process for obtaining a product*, the same product produced by a person other than the owner of the patent or his licensee shall, *unless the contrary is proved*, be taken *in any proceedings* to have been obtained by that process.

[16] Thus clearly, s 36(4) imposes on the defendants an onus to discharge a statutory presumption that they have infringed the plaintiffs' patent No MY' 481A. I would also hold that the term 'any proceedings' in this provision should obviously include proceedings such as interim injunctions as in the instant case (see Public Hearing of Urgent Proceedings, Brussels Court of First Instance on 8 October 2003 in Case No 03/454/C *Eurogenetics NV/Ratiopharma v Lundbeck* — unreported) where the burden of proof was reversed and the court granted an interlocutory injunction against the infringer). The burden imposed on a defendant is a legal burden, save that due to the absence of oral evidence at the interlocutory stage of the proceedings the defendant need only discharge such presumption upon a prima facie basis. It is my firm view that if this court is to accept the submission of the defendants that a registered patentee could invoke the above s 36(4) provision only at the trial stage of the proceedings — which may take three or more years and result in the non-enforceability of Malaysian registered patents during the pre-trial interim period — then such patent registration would be rendered virtually nugatory and commercial interests would rather move elsewhere to locate their investments.

[17] Surely, it is logically and legally right that the second plaintiff, being owner of process patent MY'481A, should have the exclusive right to use both the process as well as the product directly obtained from the process. Hence, any person using the process or sells the product obtained from the process is guilty of infringement (see ss 36(3)(a), 36(3)(b) and 58 of the Act). In my view, a process patent would have the combined effect of protecting the process as well as the product which is directly obtained from the patented process. In this regard we have to be mindful that the plaintiffs are seeking to prevent the sale of Daxotel, which is a product directly obtained from the patented process for DT. Thus, I hold that the plaintiffs are not 'seeking a remedy that is available to an owner of a product patent by the back door' as alleged by the defendants, since the scope of a process patent also

covers the product obtained directly from the process. The patent, once granted, is prima facie valid. Challenges to the validity of a granted patent have consistently been held as contributing to triable issues in a number of cases. (*Carroll & Ors v Tomado Ltd* [1971] RPC 401, *Belfast Ropework Co Ltd v Pixdane Ltd* [1976] FSR 337 and *Peaudouce SA v Kimberly-Clark Ltd* [1996] FSR 680). The defendants' claim that the grant of the US patent is prima facie evidence of non-infringement is not only incorrect in law but untenable as we are here concerned with a Malaysian patent vis-a-vis Malaysian courts. Of course oral evidence of the nature, the reach and the ramifications of the US patent even if true, could be adduced at the trial.

[18] Since the defendants assert that they have used a different process to produce the trihydrate form of Docetaxel (DT) the crucial issue for determination is, whether even upon a prima facie basis, the defendants have discharged the presumption. This would determine whether there are serious issues to be tried. The defendants contended that its US patent involves a process of purification of crude docetaxel (step 1: purification) and preparation of docetaxel trihydrate from purified docetaxel (step 2: manufacture of docetaxel trihydrate). And, that since the plaintiffs' MY'481A does not cover step 1 (purification), Dabur's US Patent does not in any way infringe the plaintiff's patent. This court, however, is not persuaded by such contention of the defendants as the process of purification could be an irrelevant factor. The irrelevance of the process of purification is explained in the Independent Expert Trevor Laird's Report (encl 12 CYS–8 p 3) which maintained that, '... the purification process set out in the Dabur Patent constitute additional pre-steps which are not relevant.'

[19] The defendants further state that step 2 of their process does not use any condition for controlling or regulating humidity and is thus different from the MY'418A patent. However, this claim is also challenged by the Independent Expert Report of Trevor Laird (encl 12 'CYS–8' p 7) which pronounced that to produce the trihydrate form of docetaxel both processes need to control the relative humidity, and that, contrary to the defendants' submissions, the humidity is controlled at the same level in both processes. Trevor Lairds reposte (see encl 12 exh 'CYS–8' pp 8–9) to the defendants' assertion, that the plaintiffs' process is crystallisation from the mixture of C1–3 alcohol and water as opposed to the defendants' method which involves precipitation from the mixture of acetonitrile and water, is that the terms 'crystallisation' and 'precipitation' are commonly used interchangeably by chemists without any distinguishing differences. They had also contended that Step 2 of the US patent uses acetonitrile to dissolve purified docetaxel but MV481A uses aliphatic alcohol as the solvent. In this regard, Trevor Laird's Report (encl 12 exh 'CYS–8', pp 4–7) states that the two types of solvents have similar properties, perform the same function in the same way

and produce the same result. The defendants appear to have submitted a total of only three batches production records dated January and February 2006 despite claiming to have been producing DT for many years past, in which case a more significant number and randomly selected batches dating back several years should have been made available. It has to be noted that the defendants merely made general reference without offering any explanation or relation to the process in the Dabur US patent. Also to be observed is that the batch records are dated around the time the present proceedings had begun and thus, could have been created for purpose of providing a defence for the defendants in this proceedings. Furthermore, there has been no credible independent third party documents to verify the process they claim to use.

[20] Surely, the defendants' claim that 'step 2 of our process does not use any condition for controlling or regulating humidity', that 'our method involves precipitation from mixture of acetonitrile and water rather than the plaintiffs' process of crystallisation from the mixture of C1–3 alcohol and water' and that the defendants 'use acetonitrile to dissolve purified docetaxel whereas MY'481A use aliphatic alcohol as the solvent' could, in my view, only be (firstly) verified and (secondly) differentiated only through the assistance of expert evidence from both sides at the trial. It is not the function of this court to assume the role of an expert in chemistry to resolve such conflicting claims now before the court. Trite law enjoins this court not to go into a mini trial on the aforesaid precise details of production of the active ingredient DT, as such issues are for trial where expert evidence would be entirely essential. The essence of the whole argument is that even if the second defendant had used Dabur's US patent, yet Trevor Laird's report that Dabur's process is substantially similar to that of the MY'481A Patent should not, at this stage of the proceedings, be brushed aside, especially as his expertise in this particular field of competency has not been challenged with any cogency. The curriculum vitae of Mr Trevor Laird (encl 12 Annex 1 — exh 'CYS 8') shows Mr Laird to be a skilled person for the purposes of the present proceedings. It is also noteworthy that Mr Laird has been instructed to provide expert evidence against the second plaintiff in unrelated proceedings in the US. Hence, based on the report of this independent expert the defendants' process would, bereft of any oral testimony, appear to infringe the plaintiffs' MY'481A patent. Also, the fact that the second defendant (Dabur) holds a US patent is quite irrelevant to the question of infringement of the Malaysian patent, since the *lex loci* of the cause of action (law of the country in which the breach occurred) is Malaysia while the *lex fori* of this action (law of the country where the action is brought) is also Malaysia, and, a fortiori, it is indeed a Malaysian registered patent (being Patent No MY'481A) that is sought to be enforced. Following the rationale in *American Cyanamid*, it is pertinent to bear in mind that the 'priority date' of the second plaintiff in Malaysia is 30 November 2004 when it became the registrant

under Malaysian Process Patent No MY'481A. This is also underscored by the fact that the first plaintiff started selling the drug Taxotera® in Malaysia in 1997, whereas the second defendant's initial sales of Dexotel in Malaysia was only in October 2005. In any event, Dabur's US patent was registered only on 4 January 2005 whereas the second plaintiff secured US patent registration on 8 February 2000.

[21] I am satisfied that the plaintiffs have proffered sufficient prima facie evidence at this early stage of the proceedings to show that the defendants have employed the same or similar process to manufacture Doxotel Trihydrate ('DT'), the active ingredient in the drug Daxotel. And also, I find that the defendants have not, upon the affidavit evidence now tendered discharged the statutory presumption, under s 36(4) of our Patents Act 1983, that their manufacturing process for Daxotel have not infringed the plaintiffs' registered patent number MY'481A. This court must have at the forefront of its mind that it should not, at this interlocutory stage of the proceedings, be dealing with the existing evidence in detail, and giving reasoned assessments to resolve conflicts of evidence in the affidavits. Clearly, just like the fact matrix in *American Cyanamid,* this is not the case where the defendants would be shut out or precluded from disputing the plaintiffs' claim at the trial if an injunction in the terms prayed is allowed.

[22] A strikingly similar fact matrix occurred in *American Cyanamid*. A company ('Cyanamid') registered a patent in the United Kingdom for the use as absorbable surgical sutures of filaments made of a particular kind of chain polymer known as 'a polyhydroxyacetic ester' ('THAE7') — The sutures were of a kind that disintegrated and were absorbed by the human body once they had served their purpose. The priority date of the patent was 2 October 1964. At that date the absorbable sutures commonly in use were made from catgut. A rival company ('Ethicon') were the main suppliers of catgut sutures in the United Kingdom. Cyanamid introduced their patented product in 1970 and by 1973 had captured some 15 per cent of the United Kingdom market for absorbable surgical sutures. In order to meet the competition from Cyanamid, Ethicon proposed to introduce their own artificial suture CXLGO. The chemical substance of which PHAE was made was a homopolymer whereas the substance of which WLG was made was a copolymer. In March 1973 Cynamid brought a quia timet action against Ethicon, claiming an injunction to restrain a threatened infringement of their patent by supplying XLG sutures to the surgeons in the United Kingdom, and gave notice of motion for an interlocutory injunction. At the hearing of the motion a large body of conflicting affidavit evidence was advanced by both parties on the issue whether the use of XLG as an absorbable surgical suture would constitute an infringement of Cyanamid's patent. The patent judge held that *on the available evidence* Cyanamid had made out a strong

A prima facie case against Ethicon and that on a balance of convenience an interlocutory injunction, on an undertaking in damages by Cyanamid, should be granted to maintain the status quo between the parties pending the trial of the action. On appeal, the Court of Appeal reversed that decision on the grounds that on the evidence Cynamid had not made out a prima facie B case of infringement and that there was well established rule of law *that a court was precluded from granting an interlocutory injunction* or from considering the balance of convenience between the parties *unless the evidence adduced at the hearing of the application satisfied the court on the balance of probabilities that, at the trial, the plaintiff would succeed in establishing his right* C *to a permanent injunction.* Cyanamid appealed.

[23] It was held by the House of Lords that the grant of interlocutory injunctions for infringement of patents was governed by the same principles as those in other actions. *There was no rule of law that the court was precluded* D *from considering whether, on a balance of convenience, an interlocutory injunction should be granted unless the plaintiff succeeded in establishing a prima facie case or a probability that he would be successful at the trial of the action.* All that was necessary was that the court should be satisfied that the claim was not frivolous or vexatious, ie that there was a serious question to be tried. E There were voluminous affidavits and exhibit filed on behalf of each party on the issue whether the use of XLG as an absorbable surgical suture would constitute an infringement of the Cyanamid's patent on the use of PHAE. On this, Lord Diplock opined that:

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> In view of the fact that there are serious questions to be tried on which the available evidence is incomplete, conflicting and untested, to express an opinion now as to the prospects of success of either party would only be embarrassing to the judge who will have eventually to try the case. The likelihood of such embarrassment provide an additional reason for not adopting the course that both Graham J and G the Court of Appeal thought they were bound to follow, of dealing with the existing evidence in detail and giving reasoned assessments of their views as to the relative strengths of each party's cases.

On adequacy of damages as a remedy

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[24] The complaint of the plaintiffs are expressed in the following persuasive language. Their sales will not only be seriously affected but the continuing infringing activities of the defendants will irreparably damage the plaintiffs' goodwill and reputation in Malaysia. And, as such reputation and I goodwill are impossible to assess and quantify, the plaintiffs cannot be adequately compensated in monetary terms (see *SAP (M) Sdn Bhd v I World HRM Net Sdn Bhd & Anor* [2006] 2 MLJ 678). Furthermore, the defendants' activities in manufacturing and selling Daxotel will destroy the plaintiffs' proprietary rights in the patent especially as they have claimed that their

product is cheaper than the plaintiffs. The plaintiffs will amongst other things set out below, lose market share in Malaysia. If the defendants are allowed to continue to sell Daxotel, having incurred virtually no up-front investment relating to research and development, the plaintiffs will be forced to match the generic-pricing in order to compete. This lower price, will be difficult, if not possible to restore to the current, pre-generic price level should the plaintiffs succeed at the trial in obtaining a permanent injunction. Consequently, if there is a premature erosion of the pricing for Taxotere® to generic levels even before the trial, it would deprive the plaintiffs of their legitimate right to the pre-generic pricing that is appropriate to recompense them for their significant research and development investment. The generally accepted norm is that drugs have a life cycle that includes a period of exclusivity during which the innovator can recoup its considerable research costs and expenses. Once the innovator's intellectual property has expired, generics enter the market, usually with significantly reduced pricing, which would usually compel the innovator to match the generic pricing in order to preserve even a small portion of its original market share.

[25] I am much persuaded by the above compelling reasons put forward by the plaintiffs' counsel in his plea for an interlocutory injunction. In *Smith Beecham Plc v Generic (UK) Ltd* [2001] Chancery Division (Patent Court), in respect of a generic anti-depressant drug, the Court was of the firm view that: 'if no injunction were granted, the patentees would very likely suffer price loss and loss of market share which would be impossible to calculate ... Also, the threat to the claimants' on-going research and the actual financial effects were likely to be much greater on the plaintiff.' In similar vein, in *Carrol & Ors v Tomado Ltd* [1971] RPC 401 it was held that damages to plaintiffs would be irreparable in that, inter alia, damage to the plaintiffs present and future business plans would be very difficult to quantify. The following passage in *American Cyanamid*, wherein the factual matrix largely rhymes with the instant case, favours the plaintiffs' case:

> ... If Ethicon were entitled also to establish themselves in the market ... until the action is tried, which may not be for two or three years yet, and possibly thereafter until the case is finally disposed of on appeal, Cyanamid, even though ultimately successful in proving infringement, would have lost its chance of continuing to increase its share in the total market ... It is notorious that new pharmaceutical products used exclusively by doctors or available only on prescription take a long time to become established in the market, that much of the benefit of the monopoly granted by the patent derives from the fact that the patented product is given the opportunity of becoming established and this benefit continues to be reaped after the patent has expired ...

[26] It is also pertinent for this court to note that once patients and doctors get used to the defendants' product, it may be commercially impracticable to

A insist on a permanent injunction after trial (see *American Cyanamid* at p 412 a–c). On the one hand we have the defendants' evidence where they have assisted Malaysia in one project to conduct R & D and clinical studies here though they have not started to conduct clinical trials. On the other hand the plaintiffs are involved in numerous ongoing clinical trials and research
B programmes with various organisations in Malaysia. The damage to plaintiffs will be much greater owing to the fact that significant sums have already been expended in current and future research. (*EAR Corporation v Protector Safety Products (UK)* [1980] FSR 574, *Improver Corp & Ors v Raymond Industrial Ltd & Anor* [1989] 1 HKC 397.
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Damages in the event defendants succeed

[27] I shall now turn to consider whether if on the other hand, should the
D defendants succeed at the trial, could damages due to them be quantified? The defendants' counsel have argued that, 'if they are forced to vacate their product from the market, the financial impact cannot be possibly quantified', yet they themselves have stated that, 'as at 29 March 2006 the volume of sales of Daxotel was RM 476,000.50' which reveal that their loss is quantifiable.
E I am mindful that the first defendant only began selling Daxotel in Malaysia in October 2005 whereas the plaintiffs' product Taxotere® has been in Malaysian market since 1997. And, that since the defendants have not expended significant resources in the development and marketing of their product their probable losses, even though quantifiable, could not be as grave
F as the plaintiffs'.

Balance of convenience

G **[28]** The injunction sought is only in respect of Daxotel but the defendants can continue selling their many other drugs to purchasers, thereby maintaining existing relationships. This will not harm the defendants' trade in a manner which cannot be compensated in damages. Thus, they would not be adversely affected substantially by the injunction. It would follow, and I
H hold, that the balance of convenience favours the plaintiffs. The ratio in *Americaya Singapore Pte Ltd v Americaya Malaysia Sdn Bhd* [1994] 1 MLJ 695, is illustrative, as therein it was held that: '... the balance of convenience lay in favour of the plaintiffs. The defendants would not be put out of business by this order as they are not dealing with 'Americaya' goods only.'
I The defendants entered the market knowing that the second plaintiff had the patent in Malaysia and would take action against any infringers, as they had done in Thailand. Furthermore, as the plaintiffs do not grant any licence on a royalty basis, damages to the plaintiffs are unquantifiable and this would far outweigh any potential damage suffered by the defendants. Also, this court

should give due recognition to the fact that the defendants began selling Daxotel in Malaysia despite being quite aware of the fact that, by doing so, they would be courting litigation.

[29] The defendants had also argued that public interest would be better served if they are allowed to continue selling Daxotel, since the defendants' Daxotel cost substantially less to cancer patients than the plaintiffs' Taxotere®. It may be true that the defendants' drug cost less to cancer patients here, but pirated compact disks, watches and DVDs sold in Petaling Street, Kuala Lumpur are also famously 'dirt cheap'. It does not then follow that because such pirated goods could save our consumers considerable sums of money, it is in the public interest to condone such activities. The defendants' contention is wholly devoid of merit. Obviously, the strong public interest factor in protecting the integrity of the patent systems and foreign commitments through mutual protocols, etc, would generally prevail over other public interest considerations. This is also underscored by the consideration that it is inimical to Malaysian economic interest not to protect its own patent system.

[30] In the event, I hold that to deny an interim injunction in the instant case will adversely impact upon the public interest in preserving intellectual property rights.

[31] Upon the usual undertaking in damages by the plaintiffs the interim injunction is thus granted as prayed in the amended prayers 1, 2 and 3 of encl 25. And, for the same compelling reasons aforesaid I am satisfied that no conditions to the granting of this interim injunction should be imposed upon the plaintiffs.

Application allowed.

Reported by Brendan Navin Siva